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12/C  
B. Webb  
8-5-03  
(AC)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
KOOP ET AL

Serial No.: 09/934,356

Filing Date: August 21, 2001

Attorney Docket No.: CTC-401

Title: ENHANCED NONINVASIVE  
COLLAGEN REMODELING

AMENDMENT AND RESPONSE TO  
PAPER NO. 11 MAILED 05/14/03

Date Mailed: July 29, 2003

Examiner: FARAH, Ahmed M.

Group Art Unit: 3739

Commissioner of Patents and Trademarks  
P.O. Box 1450  
Alexandria, VA 22313-1450

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AUG 04 2003  
TECHNOLOGY CENTER R3700

AMENDMENT AND RESPONSE TO PAPER NO. 11 MAILED 05/14/03

Dear Sir,

Applicant is in receipt of Paper No.11 mailed 05/14/03. Thank you for your continued expedient examination of the present Application.

STATEMENT OF CLAIMS STATUS

Claims 1-11 are pending.

Claims 1-11 are rejected .

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Amendment and Response to Paper No. 11 Mailed 05/14/03  
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(Nov. 12, 03)

## SUMMARY OF RESPONSE

### *Detailed Action*

#### **Claim Rejections - 35 USC § 102**

1. *Examiner States:* " Claims 1-3 and 8-10 are again rejected under 35 U.S.C. 102(e) as being anticipated by O'Donnell, Jr. U.S. Patent 6,106,614. O'Donnell, Jr. discloses apparatus and method for treating subsurface layer of skin, the method comprising the step of: applying anti-inflammatory, anti-oxidant (wound healing) pharmaceutical agent to the skin (Col. 3, lines 21-26); and irradiating the skin with laser energy sufficient to cause stimulation of collagen remodeling for the purpose of effecting the tightening of the skin and reducing wrinkles without significantly altering the epidermis (see claims 1-3). As to claim 3, O'Donnell, Jr. applies mechanical energy to the skin tissue 9Co. 6, lines 6-10). As to claim 8, his treatment reduces wrinkles. Therefore, since wrinkles result from photodamaged and/or aging skin, he provides the claimed method step."

#### **Claim Rejections - 35 USC § 103**

2. *Examiner States:* " Claims 4-6 and 11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over O'Donnell, Jr. in view of Purchio et al. U.S. Patent 5,599,788. Although O'Donnell, Jr. described above, discloses pharmaceutical agent to enhance the treatment, he does not teach the use of growth factor such as H3 protein to promote the healing process. However, Purchio et al. discloses a method of producing recombinant transforming growth factor  $\beta$ -induced H3 protein and it use to accelerate wound healing. They further teach that H3 protein may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency (Col. 4, lines 58-60). Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify O'Donnell, Jr. and apply a growth factor such as h3 protein to the skin as taught by Purchio et al. in order to accelerate the

wound healing and to enhance the over all treatment efficiency. As to claim 6 of the instant application, claim 3 of O'Donnell, Jr. teaches the claimed limitation."

3. *Examiner States:* " Claim 7 is again rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al. U.S. Patent 5,817,089 in view of Purchio et al. ('788). Tankovich et al. disclose phototherapy treatment methods for the reduction and removal of unwanted hair and the mitigation of skin conditions such as acne and seborrhea. However, they do not apply wound healing promoter composition to the skin to enhance the healing process. Purchio et al., described above, teach the use of a wound healing protein, which may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency. Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the invention of Tankovich et al. with Purchio et al. to apply a wound healing protein to the skin being treated so as to enhance the wound healing process and improve the over all treatment efficiency."

#### **Response to Arguments**

4. *Examiner States:* "Applicant's arguments filed December 31, 2002 have been fully considered but they are not persuasive. The applicant makes the following arguments: A) U.S. Patent 6,106,515 to O'Donnell, Jr. (hereafter referred as '515), fails to disclose a "wound healing composition" as recited in claim 1 and disclosed in his application. The applicant further argues that a wound healing composition as defined by the his specification includes: "a composition that amplifies the natural stimulation of growth or collagenesis caused by a wound." He further asserts that "remodeling is further enhanced by the use of a transforming growth factor which accelerates the wound healing." In response to this argument: (i) applicant's claim 1 recited the limitation "applying a wound healing composition to the skin." This is a broad limitation and

see O'Donnell,  
claim 3 →

therefore treated as broadly as claimed. (ii) U.S. Patent '515 teaches a photocoagulation method of the dermis for reducing wrinkles, the method comprising the steps of irradiating the skin with laser energy and topically applying pharmaceutical agent to the skin to promote healing (Col. 3, lines 52-61). (iii) the term photocoagulation is defined as a 'surgical coagulation of tissue by means of intense light energy, such as a laser beam, performed to destroy abnormal tissues of to form adhesive scar.' Furthermore, the prior art teaches that 'the mechanism of wrinkle reduction is based upon the reversal of the net collagen reduction stimulated by solar exposure. The net gain of collagen in the papillary dermis results from a biological response to iatrogenic injury, whether by chemical, mechanical or laser-induced trauma. The biological response is in the form of the complex sequence of events incorporated in the wound repair process culminating in, among other factors, histological, immunohistological and in situ hybridization evidence of new collagen synthesis in the papillary dermis.' Therefore, the Examiner's position is that wound healing is inherent to O'Donnell method for reducing wrinkles. B) As to claim 11, the applicant argues that a motivation to combine the teachings of the references is not immediately apparent and, therefore, the Office Action (OA) fails to establish a prima facie case of obviousness. In response to this argument, the OA clearly states the motivation for combining the references, viz. 'apply a growth factor such as H3 protein to the skin, as taught by Purchio et al., accelerates the wound healing and enhances the overall treatment efficiency.' C) As to claim 7, the applicant argues that U.S. Patent 5,599,788 to Purchio (hereafter referred as '788) is non-analogous art and "is not in the field of endeavor of the present invention or even reasonably pertinent to the problem being solved." In response to this argument, U.S. Patent '788 teaches the use of a wound healing protein, which may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency (see Col. 4, lines 58-60)."

#### Conclusion

5. *Examiner States:* “ THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).”

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07-30-03

GP 3739



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TRANSMITTAL

Dear Sir,

Enclosed please find the following documents related to the above-entitled patent application:

1.      Amendment and Response to Paper No. 11: 9 page(s); and
2.      Return Receipt Postcard.

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Respectfully submitted,

Dated: July 29, 2003

By: \_\_\_\_\_

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**CERTIFICATE OF EXPRESS MAILING**

I hereby certify that this paper and the documents referred to as attached therein are being deposited with the United States Postal Service using "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to "Commissioner of Patents and Trademarks, Washington, D.C. 20231" using express mail label number EL 977270499 US.

Signed: \_\_\_\_\_

Date Mailed: July 29, 2003